



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/790,113 | 03/02/2004 | Kazuhiro Kikuchi | 249426US | 1147 |
| 22850 | 7590 | 04/29/2005 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | AFREMOVA, VERA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,113

Applicant(s)

KIKUCHI ET AL

Examiner

Vera Afremova

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/061,321
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/02/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-4 are pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Petters et al. (IDS reference; Journal of Reproduction and Fertility Supplement. 1993, 48:61-73).

Claims are directed to a culture medium composition for in vitro produced porcine embryo wherein the medium composition comprises lactic acid or its salt and pyruvic acid or its salts. Some claims are further drawn to exclusion of glucose from the medium composition. Some claims are further drawn to particular amount of lactic acid 0.25-5.5 µl/ml of a 60% solution (0.15-3 mg/ml) and to particular amount of pyruvic acid 0.009-0.036 mg/ml.

Petters et al. disclose several culture medium compositions for in vitro produced porcine embryo (table 1, page 66 and table 3, page 69). For example: UB medium (table 3) does not contain glucose and it contains lactic acid salt 2.08 mmol/L (1.45 mg/ml) and pyruvic acid salt 0.18 mmol/l (0.016 mg/ml). The amounts are within the presently claimed ranges. The Whitten medium c and d (table 1) also comprises salts of lactic acid and pyruvic acid within the presently claimed ranges and it does not contain glucose as required by the claimed invention. Thus, the cited reference anticipates the claimed invention.

Art Unit: 1651

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,972,592 (Suarez).

Claims are directed to a culture medium composition wherein the medium composition comprises lactic acid or its salt and pyruvic acid or its salts. Some claims are further drawn to exclusion of glucose from the medium composition. Some claims are further drawn to the culture medium that is conditioned with oviductal epithelial cells.

US 5,972,592 discloses a Tyrode' balanced salt composition that comprises salts lactic acid and pyruvic acid and that does not contain glucose (col. 9, lines 40-45). Further, US 5,972,592 discloses incorporation and culturing oviductal epithelium or oviductal epithelial cells in the Tyrode' balanced salt composition (col. 10, lines 10-11; col.9, line 50). Glucose has not been used in at least some of the experiments including control. Thus, the cited patent discloses the culture medium that is conditioned with oviductal epithelial cells within the meaning of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petters et al. (IDS reference; Journal of Reproduction and Fertility Supplement. 1993, 48:61-73) taken with Kaoru Suzuku et al. (Proc. 93rd Annual Meeting of Japanese Society of Animal Reproduction. 2000, page 68), US 5,213,979 (First et al.) and US 5,972,592 (Suarez).

Claims are directed to a culture medium composition for in vitro produced porcine embryo wherein the medium composition comprises lactic acid or its salt and pyruvic acid or its salts. Some claims are further drawn to exclusion of glucose from the medium composition. Some claims are further drawn to the culture medium that is conditioned with oviductal epithelial cells. Some claims are further drawn to incorporation of particular amount of lactic acid 0.25-5.5 $\mu\text{l/ml}$ of a 60% solution (0.15-3 mg/ml) and to particular amount of pyruvic acid 0.009-0.036 mg/ml.

The reference by Petters et al. is relied upon as explained above for the disclosure of several culture medium compositions for in vitro produced porcine embryo wherein some of the medium compositions do not contain glucose and comprise salts of lactic acid and pyruvic acid. The disclosure by Petters et al. is lacking teaching about a culture medium that is conditioned with oviductal epithelial cells.

However, Kaoru Suzuki et al. teaches incorporation a medium conditioned with oviductal epithelial cells into a basal medium for in vitro produced porcine embryo (see official translation). The basal medium in the reference by Kaoru Suzuki is NCSU-37 medium that appears to contain glucose accordingly to the information in the table 1 in the reference by Petters et al.

But US 5,213,979 (First et al.) suggests incorporation of a medium conditioned with oviductal epithelial cells into the medium intended for embryos cells (see abstract; see from col. 5, lines 55, to col. 6, lines 1-6) wherein the media intended for embryos cells include the glucose lacking Tyrode's lactate-pyruvate solution as well as other basic cell culture media (col. 5, lines

Art Unit: 1651

30-41). US 5,213,979 teaches that the use a medium conditioned with oviductal epithelial cells enhances development of embryos (col. 9, lines 65-69 to col.10, lines 1-2).

Further, the cited US 5,972,592 discloses a medium composition that contains the Tyrode's lactate-pyruvate solution without glucose and a medium conditioned with oviductal epithelial cells as explained above.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to add a medium conditioned with oviductal epithelial cells taught by Kaoru Suzuku et al and/or by US 5,213,979 to the glucose-lacking and lactate-pyruvate-containing medium of Petters et al. with a reasonable expectation of success in obtaining a medium for in vitro produced porcine embryo as required by the instant claims because the prior art teaches that the use a medium conditioned with oviductal epithelial cells enhances development of embryos (US 5,213,979 [First et al]) and because compositions with medium conditioned with oviductal epithelial cells are known in the prior art as adequately demonstrated by Kaoru Suzuku et al, US 5,213,979 (First et al) and US 5,972,592 (Suarez).

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

April 27, 2005

A handwritten signature in black ink, appearing to read 'V. Afremova', with a stylized flourish at the end.

VERA AFREMOVA

PRIMARY EXAMINER